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Phone 317 276 2000

August 14, 2000

Mr. John Gomez
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Docket No. 00D-1307, CDER 67. Guidance for Industry: "Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis" published on June 14, 2000

Dear Mr. Gomez:

Per your conversation with Dr. Greg Enas, director of U.S. Regulatory Affairs, we are providing the following letter. We clarify that Lilly's response signed by Dr. Tim Franson, dated August 4, 2000, will be available to the public through the Freedom of Information and is not confidential as erroneously noted on the stationary.

Lilly appreciates the contact by the Agency to correct the note in the upper right-hand corner stating that the information is confidential. The response from Lilly was on the draft guidance document that was published in the Federal Register on June 14, 2000.

Sincerely,

ELI LILLY AND COMPANY

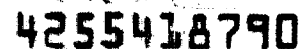


Gregory G. Enas, Ph.D.
Director, U.S. Regulatory Affairs

GGE:pb

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Date <div style="border: 1px solid black; padding: 2px; display: inline-block;">8/14/80</div>			
From (Your Name) Please Print C. Humpal		To (Recipient's Name) Please Print J. J. Jones	
Company LILLY & CO.		Company J. J. Jones	
Street Address 100 S. ELIZABETH ST. BOX 22A		Exact Street Address (We Cannot Deliver to P.O. Boxes or P.O. Zip Codes.) 5000 Fishers Lane	
City INDIANAPOLIS IN		City Fishers IN	
State IN		State IN	
ZIP Required 46204		ZIP Required 46038	
YOUR INTERNAL BILLING REFERENCE INFORMATION (optional) (First 24 characters will appear on invoice.) 123456789012345678901234			
PAYMENT 1 <input type="checkbox"/> Bill Sender 2 <input type="checkbox"/> Bill Recipient's FedEx Acct. No. 3 <input type="checkbox"/> Bill 3rd Party FedEx Acct. No. 4 <input type="checkbox"/> Bill Credit Card 5 <input type="checkbox"/> Cash/Check		IF HOLD AT FEDEX LOCATION, Print FEDEX Address Here Street Address City State ZIP Required	
SERVICES (Check only one box) 1 <input type="checkbox"/> Priority Overnight (Delivery by next business morning) 11 <input type="checkbox"/> OTHER PACKAGING 16 <input checked="" type="checkbox"/> FEDEX LETTER* 12 <input type="checkbox"/> FEDEX PAK* 13 <input type="checkbox"/> FEDEX BOX 14 <input type="checkbox"/> FEDEX TUBE 2 <input type="checkbox"/> Economy Two-Day (Delivery by second business day) 30 <input type="checkbox"/> ECONOMY* 70 <input type="checkbox"/> OVERNIGHT FREIGHT** (Confirmed reservation required) 80 <input type="checkbox"/> TWO-DAY FREIGHT** (Confirmed reservation required)		DELIVERY AND SPECIAL HANDLING (Check services required) 1 <input type="checkbox"/> HOLD AT FEDEX LOCATION WEEKDAY (Fill in Section H) 2 <input checked="" type="checkbox"/> DELIVER WEEKDAY 31 <input type="checkbox"/> HOLD AT FEDEX LOCATION SATURDAY (Fill in Section H) 3 <input type="checkbox"/> DELIVER SATURDAY (Extra charge) (Not available to all locations) 9 <input type="checkbox"/> SATURDAY PICK-UP (Extra charge) 4 <input type="checkbox"/> DANGEROUS GOODS (Extra charge) 6 <input type="checkbox"/> Special Handling 24 <input type="checkbox"/> DANGEROUS GOODS (Extra charge) 26 <input type="checkbox"/> DRY ICE 28 <input type="checkbox"/> HOLIDAY DELIVERY (if offered) (Extra charge)	
Freight Service (for packages over 150 lbs.) 70 <input type="checkbox"/> OVERNIGHT FREIGHT** (Confirmed reservation required) 80 <input type="checkbox"/> TWO-DAY FREIGHT** (Confirmed reservation required)		PACKAGES Total Total Total 1 1 1 DIM SHIPMENT (Chargeable Weight) L x W x H 12 x 12 x 12 Received At 1 <input type="checkbox"/> Regular Stop 2 <input type="checkbox"/> Drop Box 3 <input type="checkbox"/> B.S.C. 4 <input type="checkbox"/> On-Call Stop 5 <input type="checkbox"/> Station	
Government Two-Day (Restricted for authorized users only) 46 <input type="checkbox"/> GOV'T LETTER 41 <input type="checkbox"/> GOV'T PACKAGE		Emp. No. Date Federal Express Use Base Charges Declared Value Charge Other 1 Other 2 Total Charges REVISION DATE 4/94 PART #145412 EXEM 11/94 FORMAT #160 <div style="border: 2px solid black; padding: 5px; display: inline-block; font-size: 24px; font-weight: bold;">160</div> © 1993-94 FEDEX PRINTED IN U.S.A.	